SECTION 5:

510(k) Summary

APR 15 2009

Submitter: Avail Medical Products, Inc.
1900 Carnegie Avenue
Santa Ana, CA 92705

Contact: Kristen Drake
214-580-7039

Name of Device: Avail Sterile, Latex Free, Water Filled Syringe

Predicate Device: Horizon Prefilled Syringe For Inflation Of Foley Catheter, K952414

Description of the New Device: The Avail Sterile, Latex Free, Water Filled Syringe is a sterile, single patient use, disposable device that is substantially equivalent to the predicate device and other pre-filled syringes. The device is designed for catheter inflation only and is intended for single patient use as was the predicate device.

INTENDED USE OF THE NEW DEVICE: The Avail Sterile, Latex Free, Water Filled Syringe, is intended to be used to provide a sterile liquid for catheter inflation after insertion.

Comparison of the Technological Features of the New [Modified] Device and Predicate Devices: The device and the lawfully marketed predicate device contain similar materials of construction. Features of the device are comparable to those of the predicate device.

Signed,

Kristen Drake MA, CCRA, PA
Regulatory Affairs Manager
Avail Medical Products, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia A. Goeree
Regulatory Specialist
Avail Medical Products, Inc.
1900 Carnegie Avenue
SANTA ANA CA 92705

APR 15 2009

Re: K090121
Trade/Device Name: Pre-Filled Catheter Inflation Syringe
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KNY
Dated: March 13, 2009
Received: March 16, 2009

Dear Ms. Goeree:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

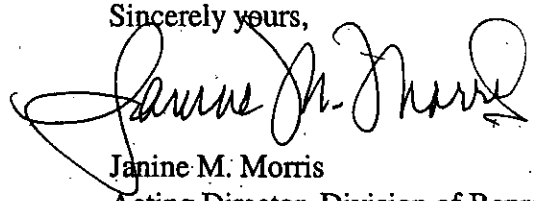
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

SECTION 4: INDICATIONS FOR USE

510(k) Number: K090121

Device Name: Sterile, Latex Free, Water Filled Syringe

Indications For Use:

The Avail Sterile, Latex Free, Water Filled Syringe is intended to be used to provide sterile water for catheter inflation after insertion.

Prescription Use X (Part 21 CFR 801 Subpart D) **and/or** **Over-the-Counter Use** ____ (Part 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090121